

## REMARKS

The first Office Action mailed on March 5, 2003 has been carefully considered and the Examiner's remarks are appreciated. Claims 1-17 were originally in the application. Claim 3 has been cancelled, and new claims 18-21 have been added. Therefore claims 1, 2, and 4-21 are presented for examination, with support for the amendments and new claims found in the Specification, Claims, and Drawings. In response to that Office Action, Applicants respectfully request reconsideration in view of the above amendments and the following remarks.

### Discussion of the Office Action

In the Office Action, the Examiner objected to claim 17 due to an informality. Claim 1 was rejected under 35 U.S.C. §102(b). And claims 1-17 were rejected under 35 U.S.C. §103(a).

### Brief Discussion of the Invention

The present invention is a porous protective sheath having active extraction media retainably contained therein for use in solid phase microextraction (SPME). The sheath permits exposure of the media to the environment (for sampling and desorption) without having to directly expose (e.g. by extension) a fragile coated fiber outside the sheath and risk breakage or other damage to the fiber, as is often seen in practice. This is possible via perforations along at least a length of the sheath through which a medium to be sampled may enter and exit the sheath and into contact with the active extraction media. Moreover, the sheath, having a sufficient strength and rigidity, is adapted to pierce through a septum such as used in gas chromatographs and other similar devices. In this manner the present invention serves to mitigate such problems as (1) fiber breakage due to fiber extension during sampling and desorption, (2) active media

coating loss caused by physical contact of the bare fiber with the sampling environment, and (3) coating slough-off during fiber extension and retraction operations caused by rubbing action between the fiber and a protective needle or tube.

#### Discussion of the Objections

Claim 17 was objected to because of the language in line 2 thereof stating, “*piercing operation with damage to said tube.*” The Examiner is correct in assuming that the Applicant’s intent was to claim piercing without damaging the tube. The appropriate correction has been made.

#### Discussion of the Rejections Under 35 USC §102

Claim 1 was rejected by the Examiner as being anticipated by “Direct Solid Phase Microextraction of Complex Aqueous Samples With Hollow Fiber Membrane Protection” to Zhang et al (hereinafter “Zhang”). In particular, the Examiner stated that “*Zhang discloses that it is highly desirable to protect a fiber of a solid phase microextraction (SPME) device*” and that “*...in order to protect the fiber, a porous member is placed around the fiber such that it forms a concentric, protective sheath about the fiber. The sheath allows specific analytes to reach the fiber, but excludes other materials.*”

It is respectfully submitted, however, that the Examiner’s reasoning is flawed in that the protection provided by the porous member in Zhang is not the same type of protection provided by the sheath of the present invention. Zhang describes a cellulose hollow membrane covering a fiber and serving to selectively allow diffusion of target analytes therethrough while filtering out interfering compounds having high molecular weights. This type of protection provided by a membrane is the selective screening protection typically provided by filters in keeping out

unwanted particles, but does not inherently provide structural support or protection to the fragile fiber. In contrast, the sheath of the present invention has a structural strength which enables and adapts it to pierce a septum of a GC injection port (see paragraphs 16 and 20 of the specification). Moreover, the same structural properties of the sheath which enable piercing of a septum, also enable mechanical shielding to withstand external forces and/or impacts, which the cellulose hollow membrane of Zhang does not provide. In this manner, the active extraction media contained within the sheath is protected from damage during all stages of the SPME process. Claim 1 has been amended to clarify this distinction, by describing the porous sheath as being “*adapted to pierce a septum*” and that it has active extraction media “*contained therein to protect the active extraction media from exposure outside the sheath and possible damage thereby.*”

Additionally, claim 1 has been amended to distinguish Zhang by providing “perforations along at least a section of length [of the porous sheath]” (emphasis added). It is respectfully submitted that while the membrane of Zhang enables diffusion of target analytes, there is no perforation or other suitably large structural opening in the membrane which enables entry and exit flow of a sampling medium (e.g. liquid or air). The perforations of the present invention enable a SPME process (including sample collection and desorption from the active extraction media) to be performed completely from within the sheath. In this manner, the active extraction media always remains protected within the safety of the sheath. Thus it is respectfully submitted that the aforementioned amendments distinguish the present invention from Zhang, and amended claim 1 is now in condition for allowance.

### Discussion of Rejections Under 35 USC § 103

Claims 1 and 10 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 5,693,228 to Koehler et al (hereinafter "Koehler") in view of U.S. Pat. No. 4,607,166 to Pawliszyn (hereinafter "Pawliszyn"). In support of his rejection, the Examiner stated that Koehler teaches "*a metal tubular casing (reference item 57)*" and that "*the purpose of the casing is to protect the fiber from damage and ensure a good seal (column 4, lines 29-31). Furthermore, though not expressly disclosed, the metal casing would have sufficient strength to pierce a septum.*" Pawliszyn was also cited by the Examiner to support this proposition.

It is respectfully submitted that the Examiner is incorrect in his reading and determination that the metal casing of Koehler (and the metal sleeve in Pawliszyn) provides damage protection to the fiber. In actuality, the placement and use of the referenced metal casing or sleeve with respect to the SPME fiber, leaves much of the lower sampling end of the fiber uncovered and exposed to external forces which can afflict damage. As described in column 4, line 26 of Koehler, "*the fiber 46 is partially enclosed within metal casing 57*" (emphasis added). Similar language is also found in Pawliszyn in column 4 lines 2-7 describing the partial enclosure. While retraction of the fiber and casing, as a unit, into a needle is described in those references, no description is provided for retraction/extension of the fiber with respect to the metal casing. Thus, the sampling end of the fiber remains extended from the metal casing for the duration of the SPME process, without any protection provided by the metal casing. This is also supported by Figure 2 of Pawliszyn illustrating the metal casing and fiber joined at an upper end by retention means 22, for movement as a unit via operation of plunger 10. Consequently, whether or not the metal casing would have sufficient strength to pierce a septum, is a speculative consideration not taught or suggested by either Koehler or Pawliszyn, and which is in fact made prohibitive by the fixed and extended fiber arrangement outside the metal casing. As noted by the court in *In re Gordon*

733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984), *"the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification."*

In contrast, the sheath of the present invention serves to contain the active extraction media within the sheath, i.e. retain and keep the active extraction media from exposure outside the sheath, as described in paragraphs 16 and 19 of the specification, in order to protect the media contained therein. This containment is maintained throughout the SPME process, which is described in paragraph 5 of the specification to include cleaning and desorption of the fiber. Thus the previously discussed amendment to claim 1 describing the porous sheath as having active extraction media *"contained therein to protect the active extraction media from exposure outside the sheath and possible damage thereby,"* and *"adapted to pierce a septum"* clarifies this distinction with the prior art.

In further support of his 103 based rejections, the Examiner also stated that *"Pawliszyn teaches that it is desired to further protect a fiber 62 using a tubular shield 108 with perforations 110 that extends beyond the end of the fiber."* However, as described in column 11, lines 9-14, the teaching of Pawliszyn leads away from the requirements of currently amended claim 1 for (1) the containment of the active extraction media (e.g. fiber) within the sheath, and (2) the carrying out of the solid phase micro-extraction process from within the sheath. In particular Pawliszyn teaches either (1) removal of the perforated tubular shield for cleaning and desorption to expose the fiber, or (2) extension of the fiber beyond the perforated tubular shield for cleaning and desorption in a GC injection port. In either case, the fiber is left exposed outside the protection of the sheath during desorption and is susceptible to the damage concerns and problems described in the specification. In contrast, the perforations required in currently amended claim 1 enable the active extraction media to carry out the SPME process from

within the sheath, without having to leave the protection of the sheath. This is true for all parts of the SPME process, including desorption, as described in paragraph 5 of the specification.

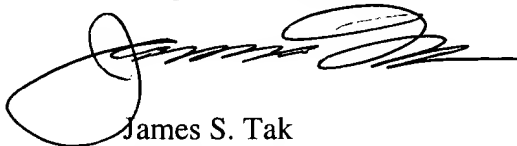
Thus, Koehler and Pawliszyn, either together or alone, do not disclose, teach or suggest all the claim elements of the respective currently amended claims 1 and 10. It is respectfully submitted, therefore, that claims 1 and 10 are allowable as amended. Furthermore, and with respect to the §103(a) rejection of dependent claims 2, 4-9, and 11-19, it is believed that the rejections are also no longer applicable because of the now amended independent claims 1 and 10.

#### Summary

Having amended the claims and/or traversed Examiner's arguments as discussed above, Applicant respectfully submits that claims 1, 2, 4-17 and new claims 18-21 are in condition for allowance. Thus, Applicants respectfully request allowance of claims 1, 2, 4-21.

In the event that the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, he is respectfully requested to initiate the same with the undersigned at (925) 422-7274.

Respectfully submitted,



Dated: April 30, 2003 By:

James S. Tak  
Attorney for Applicant  
Registration No. 46,367

Lawrence Livermore National Lab  
7000 East Avenue, L-703  
Livermore, CA 94550  
TEL: (925) 422-7274  
FAX: (925) 423-2231